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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,652	12/17/2001	Pia M. Challita-Eid	511582002500	2714

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/024,652	**Applicant(s)** CHALLITA-EID ET AL.	
	Examiner Bridget E. Bunner	**Art Unit** 1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *14 November 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *4,6,7,9,10,12,13,78 and 80-83*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). ____
13. ☐ Other: _____.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claim 5, 11, and 79 under 35 USC 101 and 35 USC 112, first paragraph is withdrawn in view of the cancellation of these claims. The rejection of claim 4 under 35 USC 102(b) is withdrawn in view of the amendment to claim 4 .

Continuation of 11. does NOT place the application in condition for allowance because: Claims 4, 6-7, 9-10, 12-13, 78, and 80-83 are rejected under 35 USC 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Claims 4 6-7, 9-10, 12-13, 78, and 80-83 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth below, one skilled in the art clearly would not know how to use the claimed invention. Applicant's arguments (27 October 2005), as they pertain to the rejection have been fully considered but are not found to be persuasive. Applicant asserts that the protein of SEQ ID NO: 2570 is useful as a therapeutic target for the treatment of prostate cancer (see Figures 10-17 of specification). Applicant also argues that antibodies have been produced against this amino acid sequence that is expressed on the surface of prostate cancer cells. At page 10 of the response, Applicant contends that well-known prostate cancer markers, including PSMA, PSCA, and PSA, are expressed on both normal and cancerous prostate. Applicant argues that in the context of immunotherapy, it is inconsequential that both normal and cancerous prostate cells express 108P5H8. Applicant indicates that on the basis of differential mRNA expression in Figure 13, cancerous cells would be expected to produce larger amounts of the 108P5H8 polypeptide and to be targeted by antibodies. Applicant also states that those of skill in the art consider such markers to be acceptable targets for immunotherapy. Applicant's arguments have been fully considered but are not found to be persuasive. Although both normal and cancerous prostate cells may express 108P5H8, there is no indication in the specification or the declarations submitted under 37 CFR 1.132 on 27 October 2005, that there is overexpression of 108P5H8 on prostate cancer cells as compared to normal prostate cells. Since 108P5H8 mRNA and protein appear to be expressed in normal prostate and cancerous prostate tissue at similar levels (see specification Figure 11B-C, for example), the asserted utility of detecting or treating a cancer that expresses the 108P5H8 protein is not a specific or substantial ("real-world") asserted utility or a well-established utility. For example, if 108P5H8 is expressed in both normal prostate and cancer prostate, one skilled in the art cannot detect or treat prostate cancer in a patient. The skilled artisan cannot determine which patient has cancer and which patient does not. The specification does not disclose any specific cancers that are associated with altered levels of the 108P5H8 polypeptide as compared to normal tissues. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease.

Furthermore, the Declarations of Dr. Karen Jane Meyrick Morrison and Dr. Steven B. Kanner filed under 37 CFR 1.132 (27 October 2005), are insufficient to overcome the rejection of claims 4, 6-7, 9-10, 12-13, 78, and 80-83, based upon 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph. Applicant states that the Meyrick Morrison declaration shows immunohistochemistry data where prostate tumor samples were tested with a polyclonal antibody which binds to SEQ ID NO: 2570. Applicant submits that the staining of the tumor sample clearly shows that the test antibody binds to the target antigen and that the protein can be detected. Applicant adds that the protein can thus be targeted. The 1.132 declaration of Dr. Kanner discusses normal tissue expression of protein targets and the utilization of therapeutic monoclonal antibodies for cancer (with examples such as Herceptin and Erbitux). Applicant's arguments and declarations submitted under 37 CFR 1.132 have been fully considered but are not found to be persuasive. Although the declaration of Dr. Meyrick Morrison does indicate that 108P5H8 protein can be detected on prostate tumor cells, there is no indication of 108P5H8 protein detection on normal prostate cells. The declaration also does not indicate if there is differential expression of 108P5H8 on prostate tumor cells vs. normal prostate cells. Furthermore, the Examiner acknowledges that therapeutic monoclonal antibodies are utilized on protein targets that are expressed on both cancerous tissue and normal tissue. However, the protein targets in these therapies are overexpressed in cancerous tissues as compared to normal tissues. Such is not the situation in the instant application. As discussed above, there is no indication in the specification or the declarations submitted under 37 CFR 1.132 on 27 October 2005, that there is overexpression of 108P5H8 on prostate cancer cells as compared to normal prostate cells. Since 108P5H8 mRNA and protein appear to be expressed in normal prostate and cancerous prostate tissue at similar levels, the asserted utility of detecting or treating a cancer that expresses the 108P5H8 protein is not a specific or substantial ("real-world") asserted utility or a well-established utility.

It is noted that several of the references cited by Applicant at pages 7-10 of the response were not included with the submission of the response (Gygi et al., $_2$Futcher et al., Orntoft et al., Costello et al.).